UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL. *Plaintiffs*, v. HEC PHARM CO., LTD., ET AL. *Defendants*.	Civil Action No: 15-cv-5982 (PGS)(TJB) **MEMORANDUM AND ORDER**

SHERIDAN, U.S.D.J.

This matter comes before the Court on Joint Claim Construction submitted by Boehringer Ingelheim Pharmaceuticals, Inc., et al. (hereinafter "Boehringer") and HEC Pharm Co., LTD., et al. (hereinafter "Defendants") pursuant to L. Pat. R. 4.3. (*See* Dkt. No. 332). The Joint Claim Construction submitted by the parties concerns with the following U.S. Patents—7,407,955 ("the '955 patent"), 8,119,648 ("the '648 patent"), 8,673,927 ("the '927 patent"), 8,853,156 ("the '156 patent"), 8,846,695 ("the '695 patent"), 8,178,541 ("the '541 patent"), and 9,173,859 ("the '859 patent").

On December 9, 2016, in a consolidated letter to the Court, the parties requested this Court to construe two claim terms—(i) "A method of treating type 2 diabetes" and related terms, as recited in the '927, '859 and '695 patents; and (ii) "optionally in combination with metformin" as recited in claim 14 of the '859 patent. (*See* Dkt. No. 390). On December 12, 2016, pursuant to L. Pat. R. 4.6, a *Markman* Hearing was conducted before the Court for the aforementioned two claim terms. These terms are construed below.

STANDARD OF REVIEW

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claim construction determines the correct claim scope, and is a determination exclusively for the court as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The focus in construing disputed terms in claim language "is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term[s] to mean." *Id.* at 986.

To determine the meaning of the claims, courts start by considering the intrinsic evidence. *Phillips*, 415 F.3d at 1313; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Comms. Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861.

The claims themselves provide substantial guidance in determining the meaning of particular claim terms. *Phillips*, 415 F.3d at 1314. First, the context in which a term is used in the asserted claim can be very instructive. *Id.* Other asserted or unasserted claims can aid in determining the claim's meaning because claim terms are normally used consistently throughout a patent. *Id.* Differences among claims can also assist in understanding a term's meaning. *Id.* For example, when a dependent claim adds a limitation, there is a presumption that the independent claim does not include that limitation. *Id.* at 1314-15.

"[C]laims 'must be read in view of the specification of which they are a part.'" *Id.* at 1315 (quoting *Markman*, 52 F.3d at 979). "[T]he specification 'is always highly relevant to the

claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. *Id.* at 1316. In these circumstances, the inventor's lexicography governs. *Id.* The specification may also resolve the meaning of ambiguous claim terms "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). But, "[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims." *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)); *also see Phillips*, 415 F.3d at 1323 ("although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.").

The prosecution history is another tool to supply the proper context for claim construction. It "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower that it would otherwise be." *Phillips*, 415 F.3d at 1317.

"Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Although extrinsic evidence can be useful, it is "less significant than the intrinsic record

in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862).

Dictionaries and treatises may aid a court in understanding the underlying technology and the manner in which one skilled in the art might use claim terms, but dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id.* at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition are entirely unhelpful to a court. Id.

Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.* The Supreme Court recently explained the role of extrinsic evidence in claim construction:

> In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. . . . In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the "evidentiary underpinnings" of claim construction that we discussed in *Markman*, and this subsidiary fact finding must be reviewed for clear error on appeal.

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S.Ct. 831, 841 (2015).

As is sometimes the case, the claim terms requiring construction may have been the subject of a prior claim construction proceedings by other district courts, or even the same court. While rulings of the Federal Circuit on issues of claim construction for a given patent are binding on later district courts analyzing the same patent, interpretations of the same or other district courts of the same terms in the patent or patent family are generally not binding. *See Shire Dev. LLC v. Amneal Pharms. LLC*, Civ. No. 15-2865, 2016 WL 4119940, at *2 (D.N.J. Aug. 2, 2016);

see also Ravo v. Tyco Healthcare Group LP, Civ. No. 11-1637, 2013 WL 3326657, at *6 (W.D. Pa. Mar. 13, 2013). However, the interpretations of the same or other district courts are generally considered to be highly relevant and persuasive authority. *Id.*

Overall, in construing the claims, "[t]he judge's task is not to decide which of the adversaries is correct. Instead, the judge must independently assess the claims, the specification, and if necessary the prosecution history and relevant extrinsic evidence, and declare the meaning of the claims." *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1556 (Fed. Cir. 1995).

ANALYSIS

With the above standard in mind, the Court has construed the following claim terms that the parties submitted before the Court—(i) "A method of treating type 2 diabetes" and related terms, as recited in the '927, '859 and '695 patents; and (ii) "optionally in combination with metformin" as recited in claim 14 of the '859 patent.

1. "A method of treating type 2 diabetes"

Both parties agree that claim terms—"A method treating type 2 diabetes," "A method for treating type 2 diabetes mellitus," "A method of treating type II diabetes mellitus," and "A method of treating type 2 diabetes or prediabetes," as recited in patents '859, '927 and '695 are at issue and subject to the same argument.[1] For purposes of convenience and simplification, the

[1] All of the foregoing claim variations are at issue and subject to the same argument: "A method of treating type 2 diabetes" ('859 patent, claims 1, 20); "A method for treating type 2 diabetes mellitus" ('695 patent, claims 1–2); "A method of treating type II diabetes mellitus" ('927 patent, claim 1); "A method of treating type 2 diabetes or prediabetes" ('927 patent, claims 10, 20). For convenience and clarity, Boehringer's brief only refers to them as "method of treating type 2 diabetes," term, but notes that it should be understood that the arguments made with respect to that term are applicable to all of the claim variations of this term at issue in each of the above listed patent claims. (*See* Pls. Br. at 12, ECF 346; *also see* Def. MSN's Br. at 3, ECF 342) ("The claim terms "method of treating"/"method for treating"/"method of treating and/or preventing" appear in the preambles of all claims in the four method of use patents asserted against MSN and other defendants.").

Court has construed the claim term "A method of treating type 2 diabetes," as recited in Claim 1 of the '859 patent; but notes that the same analysis applies to the similar terms noted in the '695 patent and the '927 patent.

As a preliminary matter, the Court notes that the '859 patent, issued on November 3, 2015, is a continuation of patent application 12/946,193 ("Parent Application"), which issued into the '927 patent on March 18, 2014. As a continuation of the Parent Application, the disclosure of the '859 patent is the same as the disclosure of the '927 patent. (*See* Manual of Patent Examining Procedure ("MPEP") 201.07).[2] With respect to the '695 patent, issued on September 30, 2014, this patent claims priority to a PCT Application (PCT/EP2010/050103), and does not refer back to either the '859 patent or the '927 patent. As such, the disclosure of the '695 patent may not be identical to the disclosure of the '859 patent or the '927 patent.

Claim 1 of the '859 patent is the representative claim, which states:

> **A method of treating type 2 diabetes** comprising
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> administering to a patient in need thereof (a)1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a therapeutically active salt thereof, in an oral dosage of 2.5 mg or 5 mg, and (b) metformin
>
> wherein the dose of metformin is 100 mg to 500 mg or 200 mg to 850 mg (1-3 times a day), or 300 mg to 1000 mg once or twice a day, or as delayed-release metformin in a dose of 500 mg to 1000 mg once or twice a day, or 500 mg to 2000 mg once a day, or
>
> wherein the dose of metformin is 500 mg, 850 mg or 1000 mg as a single dose with a total daily dose of metformin of 500-2850 mg, or 500 mg, 1000 mg, 1500 mg or 2000 mg metformin in delayed release form, or
>
> wherein the dose of metformin is 500 mg to 1000 mg.

[2] MPEP 201.07. "A continuation application is an application for the invention(s) disclosed in a prior-filed co-pending non-provisional application, international application designating the United States, or international design application designating the United States."

Defendant MSN argues that the claim term "A method of treating type 2 diabetes" should be construed to mean, "A method of treating that does not include using lingaliptin as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both lingaliptin and metformin is appropriate." (*See* Def. MSN's Br. at 3, ECF 342). In support of its position, Defendant MSN relies on extrinsic evidence of Abbreviated New Drug Application (ANDA) submissions to the Food and Drug Administration (FDA).

In particular, Defendant MSN relies on Section 4.2a of Form 3542 submitted to FDA by Boehringer, which requires a "[New Drug Application] NDA holder to 'identify the use with specific reference to the approved labeling for the drug product.'" One section in Form 3542, known as a "use code," describes the scope of the patent. Defendant MSN asserts that since Boehringer did not disclose in the Form 3542 that administration of lingaliptin can be done adjunct to diet and exercise, the scope of the '859 patent does not cover administration of lingaliptin with diet and exercise. (*See* Def. MSN's Br. 12-13). That is, based on the reading of the claims, the lingaliptin, or lingaliptin/metformin, is used only as a primary pharmacologic agent, or in combination with other pharmacological agents, especially since the specifications of the '859 and '927 patents do not mention diet and exercise as a treatment for type 2 diabetes. (*See* Def. MSN's Br. at 5, 7, 8).

In contrast, Boehringer argues that no claim construction is necessary for the claim term "A method of treating type 2 diabetes." Instead, plain and ordinary meaning of these terms is sufficient. In particular, Boehringer asserts that the specifications of the '859, '927 and '695 patents do not require that lingaliptin only be used in patients to whom diet and exercise are not recommended. For example, the specification of '695 patent requires that when diet and exercise are not effective for treating type 2 diabetes, and conventional antidiabetic drugs are not

effective, then DPP-IV inhibitors disclosed in the '695 patent should be used. (*See* the '695 patent, col. 1, ll. 19-26). In addition, Boehringer argues that labels for the conventional drugs, metformin and Januvia®, which are approved for the treatment of type 2 diabetes, indicate that the aforementioned drugs are to be taken as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. (*Id.* at 10). As such, the claim term "A method of treating type 2 diabetes" does not necessarily limit the use of lingaliptin without diet and exercise.

The Court agrees with Boehringer's position, and finds that the claim term "A method of treating type 2 diabetes," does not require claim construction and should be given plain and ordinary meaning. The Court recognizes that, unlike the specification of the '695 patent, the specifications of the '859 and '927 patents do not specifically mention that for treating type 2 diabetes, lingaliptin should be used in conjunction with diet and exercise. However, the Court notes that the aforementioned patents also do not disavow or disclaim the use of lingaliptin with diet and exercise. For example, during prosecution of the aforementioned patents, the Applicant, through its counsel, did not make any assertions or statements to overcome the prior art and/or non-prior art rejections, made by the Examiner under 35 U.S.C. §§ 101, 102, 103, and 112, to assert that lingaliptin cannot be used with diet and exercise. [3,4,5]

Further, the Court notes that one of ordinary skill in the art understands that a pharmaceutical drug, such as lingaliptin, used for treating type 2 diabetes, could be used in conjunction with diet and exercise because diet and exercise are main elements of good health, well-being and generally the first line of treatment for type 2 diabetes.

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[3] *See* Prosecution History of the '859 patent (U.S. Pat. App. 14/161,007), Applicant's Arguments/Remarks filed on Feb. 8, 2015; July 10, 2015; and July 29, 2015.

[4] *See* Prosecution History of the '927 patent (U.S. Pat. App. 12/946,193), Applicant's Arguments/Remarks filed on Nov. 15, 2010; Sept. 28, 2012; April 26, 2013; and Sept. 30, 2013.

[5] *See* Prosecution History of the '695 patent (U.S. Pat. App. 13/143,370), Applicant's Arguments/Remarks filed on July 6, 2011; July 8, 2013; and Dec. 6, 2013.

Accordingly, the Court finds that "A method of treating type 2 diabetes," does not require claim construction and should be given its plain and ordinary meaning.

2. "optionally in combination with metformin"

Claim 14 of the '859 patent states,

> An oral tablet formulation comprising 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in an amount of 2.5 mg or 5 mg **optionally in combination with metformin**, and a pharmaceutically acceptable carrier or diluent.

Boehringer argues that the claim term, "optionally in combination with metformin" should be construed to mean "may be combined with metformin." (*See* Pls.' Br. at 6, ECF 346). Whereas, Defendants argue that the aforementioned claim term should be construed to mean "optionally in combination with metformin, for use in combination therapy." (*See* Defs.' Br. at 17, ECF 345).

The '859 patent discloses DPP-IV inhibitors that are structurally distinguishable from conventional DPP-IV inhibitors, and when combined with other pharmaceutical active substances, the DPP-IV inhibitors disclosed in the '859 patent have exceptional potency and a long-lasting effect with pharmacological properties. (*See* the '859 patent, col. 7, ll. 58-65). Depending on particular functional disorders diagnosed for a patient, the DPP-IV inhibitors may be combined with other antidiabetic substances. (*Id.* at col. 8, ll. 1-5).

For example, (i) for lowering lipid level in the blood, HMG-COA reducatase inhibitors may be combined with the DPP-IV inhibitors; (ii) for lowering blood pressure and treating heart failures, beta-blockers such as atenolol and bisoprolol may be combined with the DPP-IV inhibitors; and (iii) for treating obesity, sibutramine and tetrahydrolipstain may be combined

with the DPP-IV inhibitors. (*Id.* at col. 14, ll. 17-20, 35-37 and 61-62; col. 15, ll. 12-13). Depending on whether the DPP-IV inhibitors are being administered intravenously or orally, combination of the other active substance may be formulated with one or more inert conventional carriers and/or diluents. (*Id.* at col. 8, ll. 10-20).

For purposes of lowering the blood sugar level or the lipid level in the blood, the DPP-IV inhibitors may be combined with an antidiabetic substance such as metformin. (*Id.* at col. 8, ll. 1-5). For example, in a preferred example, metformin in doses of about 100 mg to 500 mg or 200 mg to 850 mg (1-3 times a day), may be combined with the DPP-IV inhibitors disclosed in the '859 patent. (*Id.* at col. 14, ll. 5-10; col. 15, ll. 33-40). Lastly, the '859 patent discloses that patients with type 2 diabetes, or with pre-diabetes, are treated either with a DPP-IV inhibitor on its own, with metformin on its own, or with a combination of DPP-IV inhibitor and metformin. "Evidence that the combination is appropriate and effective can be found in the fact that the combination of a DPP-IV inhibitor with metformin leads to a *significantly greater* reduction in the fasting glucose and/or non-fasting glucose and/or the HbA1c value than either the DPP-IV inhibitor alone or metformin alone." (*Id.* at col. 20, ll. 42-51).

During prosecution of the '859 patent, claim 14 (originally numbered as claim 36) was rejected twice by the Examiner at the Patent Office. First, on November 19, 2014, the Examiner rejected claim 14 on two grounds, namely—(i) a nonstatutory double patenting rejection, which indicated that claim 14 was unpatentable over certain claims of U.S. Pat. 8,178,541 (commonly assigned to Boehringer Ingelheim Pharma Gmbh & Co. Kg), and (ii) an anticipation rejection, which indicated that pursuant to 35 U.S.C. § 102(b) claim 14 was anticipated by U.S. Pat. Pub. 2004/0097510 ("Himmelshach"). (*See* Non-Final Office Action, mailed Nov. 19, 2014). Thereafter, on April 16, 2015, claim 14 was rejected under nonstatutory double patenting

rejection over certain claims of U.S. Pat. 8,673,927. (*See* Final Office Action, mailed April 16, 2015).

In response to the Examiner's anticipation and nonstatutory double patenting rejection, Applicant, on behalf of his counsel, does not limit the scope of the claim term "optionally in combination with metformin," recited in claim 14, to mean the *combination* of DPP-IV inhibitor-metformin for use in treating type 2 diabetes, as alleged in Defendants' brief. (Defs.' Br. at 22-25, ECF 345). Instead, via its amendment, Applicant only further defines the amount required for the DPP-IV inhibitor to be 2.5 mg or 5 mg. Applicant did not address or further limit the term "optionally in combination with metformin."

The Court notes that the '859 patent does not specifically define the term "optionally." However, the '859 patent does discuss the combination of the DPP-IV inhibitor with another active ingredient (e.g., beta-blockers) depending on what resultant effect (e.g., lowering lipid level, lowering blood pressure, etc.) is desired, and whether the DPP-IV inhibitor is being administered intravenously or orally. (*See* the '859 patent, col. 8, ll. 10-20; col. 14, ll. 17-20, 35-37 and 61-62; col. 15, ll. 12-13). As such, indicating that the DPP-IV inhibitor can be combined with one active ingredient and/or another, in various combinations, in order to achieve a desired result.

Section 2173.05(h) of the MPEP, titled Alternative Limitations, indicates that "[a]n alternative format which requires some analysis before concluding whether or not the language is indefinite involves the use of the term "optionally." In *Ex parteCordova*, 10 USPQ2d 1949 (Bd. Pat. App. & Inter. 1989) the language "containing A, B, and optionally C" was considered acceptable alternative language because there was no ambiguity as to which alternatives are covered by the claim.

Here, the Court notes that the claim term states, "An oral tablet formulation comprising [a DPP-IV inhibitor] [...] *optionally* in combination with metformin, and a pharmaceutically acceptable carrier or diluent." As such, the oral tablet formulation of claim 14 comprises the DPP-IV inhibitor, which may be combined with metformin and a carrier or diluent. That is, the DPP-IV inhibitor does not have to be combined with metformin and a carrier or diluent in order to form the oral tablet. Instead, the oral tablet must include the DPP-IV inhibitor, in amount of 2.5 mg or 5 mg, which may or may not be combined with metformin and a carrier or diluent.

Such an interpretation of the aforementioned term is supported by the specification of the '859 patent, which discloses that patients with type 2 diabetes are treated either with a DPP-IV inhibitor on its own, with metformin on its own, or with a combination of DPP-IV inhibitor and metformin. (*See* the '859 patent, col. 20, ll. 42-45). As such, the Court does not find Defendants' argument persuasive to construe the aforementioned term for use in "combination therapy" because examples disclosed in the specification are generally not read into the claims. *Comark*, 156 F.3d at 1187 ("[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims."); *also see Phillips*, 415 F.3d at 1323.

As such, the Court construes the term "optionally in combination with metformin," as recited in claim 14 of the '859 patent, to mean "may be combined with metformin."

ORDER

IT IS on this 4 day of January, 2017,

ORDERED that "A method of treating type 2 diabetes" and related terms, as recited in the '927, '859 and '695 patents, do not require claim construction and should be given its plain and ordinary meaning; and it is further

ORDERED that "optionally in combination with metformin," as recited in claim 14 of the '859 patent to mean "may be combined with metformin."

Peter G. Sheridan

PETER G. SHERIDAN, U.S.D.J.